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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,874	07/24/2001	Stuart D. Edwards	9222.16792	4783
26308	7590	05/12/2004	EXAMINER	
RYAN KROMHOLZ & MANION, S.C. POST OFFICE BOX 26618 MILWAUKEE, WI 53226			PEFFLEY, MICHAEL F	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 05/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/911,874	EDWARDS ET AL.	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 July 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's amendments and comments, received March 15, 2004, have been fully considered by the examiner. The following is a complete response to the March 15, 2004 communication.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the penetrating electrodes located on the expandable surface and the flexible circuit penetrating electrodes must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-6, 19, 53, 53 and 81 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to disclose penetrating electrodes which are distributed on a surface of the expandable

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member, or which cover a substantial portion of the expandable member. Applicant has amended independent claims 1 and 50 to recite an energy delivery device adapted to penetrate tissue (as shown in figure 11). The electrodes which penetrate tissue are provided through apertures in the expandable member and are therefore not on the surface of the expandable member (i.e. balloon). Also, there is no disclosure of a flexible circuit electrode which is configured to penetrate tissue as now set forth in claim 81.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7-18, 20-24, 26-36, 39, 45-48, 50, 51, 54-57, 59-68, 77, 78 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards ('197).

As best shown in Figure 3C, Edwards provides a device comprising an expandable member (137) and an energy delivery device comprising a plurality of electrodes (139) coupled to the expandable member and adapted to penetrate tissue. There is also a flexible coupling member (124) coupled to the expandable member which includes a lumen for delivering a fluid (i.e. cooled saline) to the expandable member.

The examiner maintains that given its size and application, the Edwards ('197) is inherently capable of being provided in a sphincter to dilate a treat a sphincter as set

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forth in the claims. That is, the Edwards device is deemed inherently capable of meeting the intended use limitations set forth in the application claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-6, 19, 25, 37-43, 52, 53, 58, 69-76 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards ('197) in view of the teaching of Edwards ('730).

Edwards ('197) fail to specifically disclose the use of electrodes on the surface of the balloon, and the use of a porous balloon.

With regard to the surface electrodes, the examiner maintains that the applicant is improperly combining different embodiments as there is no support in the original specification for penetrating electrodes which cover a surface of the expandable member. Rather, applicant has two separate embodiments: one with penetrating electrodes extending through the expandable member, and one with electrodes which are incapable of penetrating tissue and are located on the surface of the expandable member.

Edwards ('730) discloses and teaches the latter of the two embodiments, and specifically teach of providing the balloon with a porous surface for providing electrolytic solution to tissue being treated with RF electrodes. Further, Edwards ('730) disclose

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various alternative energy sources (i.e. microwave, ultrasound, etc.) for treating tissue.

This reference has been addressed in the previous Office action.

To have provided the Edwards ('197) device with electrodes on the surface of the balloon for treating tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Edwards ('730). To have further provided the Edwards ('197) device with a porous balloon to provide electrolytic solution to the electrodes to enhance the treatment would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Edwards ('730).

Claims 44, 49, 77 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards ('197) in view of the teaching of Edwards et al ('672).

The Edwards ('197) device has been addressed previously. Edwards fails to specifically disclose a mechanical expansion means for the expandable device (i.e. balloon).

Edwards et al ('672) disclose a substantially identical device which includes an expandable member (i.e. balloon) which is provided with a plurality of energy transmitting devices for treating tissue. The structure is substantially identical to the Edwards ('197) device, and further teaches the use of a mechanical expansion means for expanding the balloon (see Figure 4A).

To have provided the Edwards ('197) device with a mechanical means for expanding the balloon into its expanded shape would have been an obvious

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modification for one of ordinary skill in the art since Edwards et al ('672) teaches the use of such a mechanical expander in an analogous balloon device.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-88 of U.S. Patent No. 6,056,744. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of the arms having a particular spring force is deemed to be an obvious design modification and/or inherent property of the system.

Claims 1-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-51 of U.S. Patent No. 6,254,598. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of the arms having a particular spring force is deemed to be an obvious design modification and/or inherent property of the system.

Claims 1-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,423,058. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of the arms having a particular spring force is deemed to be an obvious design modification and/or inherent property of the system.

Claims 1-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40 of U.S. Patent No. 6,440,128. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of the arms having a particular spring force is deemed to be an obvious design modification and/or inherent property of the system.

Claims 1-82 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09/776,140. Although the conflicting claims are not identical, they are not patentably distinct from each other because the particular spring force is deemed an obvious design modification and/or inherent property of the system.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-82 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09/971,485. Although the conflicting claims are not identical, they are not patentably distinct from each other because the particular spring force is deemed an obvious design modification and/or inherent property of the system.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-82 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/084,590. Although the conflicting claims are not identical, they are not patentably distinct from each other because the particular spring force is deemed an obvious design modification and/or inherent property of the system.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

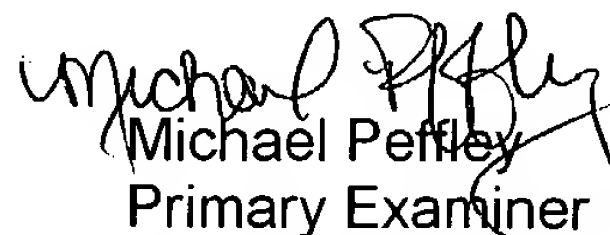
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Peffley
Primary Examiner
Art Unit 3739

mp
May 10, 2004